

# Descripción general de la FDA sobre la Trazabilidad de Alimentos asistida por tecnología

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Webinar de IICA

13 de julio de 2023



**U.S. FOOD & DRUG  
ADMINISTRATION**

# Promoviendo la trazabilidad



- Menos enfermedades/muertes por alimentos
  - Identificación más rápida de la fuente de contaminación
  - Retirada rápida de alimentos contaminados del mercado
- Limita el alcance de los retiros de productos
- La información armonizada permite que la FDA establezca vínculos a lo largo de la cadena de suministro de manera más rápida
- Se alinea con los enfoques actuales de la industria
- Mejora la capacidad de realizar investigaciones de causa raíz para identificar y aplicar lecciones aprendidas luego de un brote
- Proporciona una mayor transparencia e inteligencia de la cadena de suministro

# Promoviendo la trazabilidad



- La Norma final de Trazabilidad de Alimentos es un paso clave
- La iniciativa de la Nueva Era de la Inocuidad Alimentaria más Inteligente se basará en este trabajo fundamental
- No indica tecnologías específicas para mantener registros
- El objetivo final es lograr una trazabilidad de extremo a extremo en todo el sistema alimentario.

# ¿A quién impactará la Norma De Trazabilidad de los Alimentos?



- Personas que fabrican, procesan, empacan o almacenan alimentos en la Lista de Trazabilidad de Alimentos
- Cubre toda la cadena de suministro de alimentos
- Incluye tanto entidades extranjeras como nacionales
- Pueden corresponder exenciones totales o parciales

# ¿Cuándo debe cumplir la industria?

**20 de enero de 2026**



- Corresponde a todas las empresas
- Permite tres años para que las entidades cubiertas trabajen con la cadena de suministro
- Educaremos antes de regular y durante el proceso
- La FDA ya comenzó la planificación de la implementación

# LISTA DE TRAZABILIDAD DE LOS ALIMENTOS

Queso (elaborado con leche pasteurizada), fresco blando o blando no madurado	Tomates (frescos)
Queso (elaborado con leche pasteurizada), blando madurado o semiblando	Frutas de árboles tropicales (frescas)
Queso (elaborado con leche sin pasteurizar), que no sea queso duro	Frutas (recién cortadas)
Huevos con cáscara	Hortalizas distintas de las de hoja verde (recién cortadas)
Mantequillas de frutos secos	Peces, especies productoras de histamina (fresco y congelado)
Pepinos (frescos)	Peces, especies potencialmente contaminadas con ciguatoxina (fresco y congelado)
Hierbas (frescas)	Peces, especies no asociadas con histamina o ciguatoxina (fresco y congelado)
Hortalizas de hoja verde (frescas)	Pescado ahumado (refrigerado y congelado)
Hortalizas de hoja verde (recién cortadas)	Crustáceos (frescos y congelados)
Melones (frescos)	Moluscos, bivalvos (frescos y congelados)
Pimientos (frescos)	Ensaladas estilo delicatessen listas para su consumo (refrigeradas)
Semillas germinadas (frescas)	

# Exenciones



Exenciones legales	Exenciones legales parciales
Huertas que le venden alimentos directamente a los consumidores	Ciertos RACs (productos agrícolas crudos) mezclados (frutas y vegetales no)
Alimento producido/empacado/etiquetado en la huerta	Barcos pesqueros, alimentos obtenidos de barcos pesqueros
	Programas "de la huerta a la escuela/de la huerta a la institución"
Otras exenciones	Otras exenciones parciales
Establecimientos pequeños	Establecimientos de venta al por menor o restaurantes que compran alimentos directamente a una huerta
Productos y huevos con cáscara sometidos a determinados procesamientos	Establecimientos de venta al por menor o restaurantes que compran alimentos a otro establecimientos de venta al por menor o restaurante de forma puntual
Productos clasificados por la FDA como "raramente consumidos crudos".	Alimentos sometidos o que se someterán a eliminación de microorganismos
Moluscos bivalvos crudos	Alimentos que cambian o cambiarán y ya no formarán parte de la FTL
Alimentos sometidos a eliminación de microorganismos	Alimentos para investigación o evaluación
Alimentos regulados por el USDA	
Transportistas de alimentos	
Establecimientos alimentarios sin ánimo de lucro o para consumo personal	

# Conceptos clave de la Norma Final

- Marco de Eventos de Seguimiento Críticos (CTE) y Elementos de Datos Clave (KDE)
- Lenguaje estándar
- Vinculación de información mediante código de lote
- Registros electrónicos y/o en papel
- Registros proporcionados a la FDA en un plazo de 24 horas
- Identificación y retiro más rápido de productos.



# Énfasis en...



**Mantener y  
compartir los  
KDE**



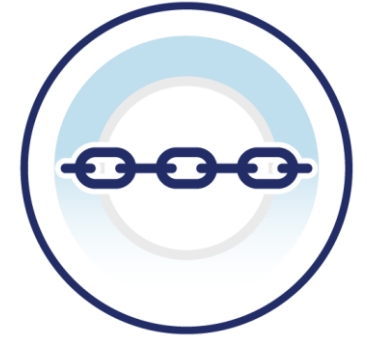
**Código de Lote  
de Trazabilidad  
(TLC)**



**Fuente del  
Código de Lote  
de Trazabilidad  
(Fuente de TLC)**



**Plan de  
trazabilidad**



**Trabajar con sus  
socios en la  
cadena de  
suministro**

# Estado actual



Exit Payment To Page 1 of 2

LOCAL : 615-284-2888 8111 TN  
TOLL : 800-824-3388  
FAX : 615-284-3388

Ship To: Distributor A  
NASHVILLE TN 37210  
489623-2740

Invoice No. 26587 Invoice Date 4/26/19 Customer No. 739 Order Date 4/26/19 P.O. Number 1150872/L22146 UNASSIGNED NET 29 DAYS DUE DATE: 4/24/19 MFC

SPECIAL INSTRUCTIONS: 1150872 FRIDAY 04/26/2019 5284645

Item Number	Quantity Ordered	Quantity Shipped	Pack Size	Item Description	Unit Weight	Extended Weight	Unit Price	Extended	ST
885802	170	170	250	TOMATOES UTILITY 250	-7382264				
887113	180	180	100	250 CAPE					
887188	60	60	120	TOMATO GRAPE 120	-3798291				
881291	60	60	250	Tomatoes Grape 12/1 Pint	-4959283				
882311	180	180	250	TOMATOES 250 250	-4851412				
886688	10	10	250	250 ROMA CPE - NOT A UTILITY	-3449693				
881450	8	8	200	TOMATOES Sanded 250 Fresh	-2093730				
881707	40	40	20	4x4 2-Layer DEEP RED V8	-3064987				
881822	180	180	20	TOMATO DEEP RED VINE RIPE	-8331888				
881482	180	180	200	TOMATOES 5x5 2-Layer	-1079219				
881482	180	180	250	250 4x6 250	-132782				

MARKETPLACE PRICE.

Driver Cash Amount Check Amount Check your merchandise before signing Customer Signature: Total weight Sub Total

Receiving for Distr. A

Tomato

Row 3

NASHVILLE, TN 37210 PHONE: 615-284-2888

P.O. # 1150872  
D.C. # L22146  
P.O. DATE 4/25/2019  
PHONE  
FAX #  
BROKER'S PHONE #  
BROKER'S FAX #  
P.O. Type D (Delivery)

TERMS: N/ LEAD: DAYS FRT:

BROKER BUYER: AN R.R. CARB: R.R. SEAL#:

SHIP DATE: 4/25/2019  
DELIVERY DATE: 4/26/2019

UPC NUMBER	ITEM DESCRIPTION	CL	ITEM	SLOT	LOC	ORDER	RECD	AVG WGT	WGT REC
9500	TOMATO CAPE CT UBU	0	22553	C	01C075A	170	170	4598.00	
	T1/H1 10/4 Shelf Life	0							
	Quality:								
	TOMATO GRAPE 16LB	0	9500	22542	C	01C064A	180	180	1980.00
	T1/H1 8/7 Shelf Life	0							
	Quality:								
	TOMATO GRAPE 12PT	0	9500	22533	C	01C073A	60	60	660.00
	T1/H1 12/12 Shelf Life	0							
	Quality:								
	TOMATO LARGE ROUNDS 25LB	0	9500	22931	C	01C069A	60	60	1560.00
	T1/H1 8/10 Shelf Life	0							
	Quality:								
	TOMATO ROMA 25LB	0	9500	22490	C	01C072A	180	180	4860.00
	T1/H1 10/5 Shelf Life	0							
	Quality:								
	TOMATO SELECT 25LB UBU	0	9500	22556	C	01C079A	10	10	270.00
	T1/H1 10/4 Shelf Life	0							
	Quality:								
	TOMATO 4X4	0	9500	22500	C	01C078A	8	8	176.00
	T1/H1 8/6 Shelf Life	0							
	Quality:								
	TOMATO 4X5 CCF	0	9500	22507	C	01C077A	40	40	880.00
	T1/H1 8/6 Shelf Life	0							
	Quality:								
	TOMATO 5x5 20LB LAYER	0	9500	22511	C	01C076A	164	164	1976.00
	T1/H1 8/6 Shelf Life	0							
	Quality:								

Distributor A Nashville TN

P.O. #  
D.C. #  
CONFIRMED  
P.O. DATE  
PHONE #  
FAX #  
BROKER'S PHONE #  
BROKER'S FAX #  
P.O. Type

RECEIVING PURCHASE ORDER

TERMS: N/ LEAD: DAYS FRT:

CBO BROKER: BUYER: AN R.R. CARB: R.R. SEAL#:

SHIP / DELIVERY DATE: 4/25/2019

ITEM	QTY	UNIT	COOL	RYAN	S/C	FREIGHT	ICE	BLK	CH
0 CAPE CT UBU	170	170							
0 GRAPE 16LB	180	180							
0 GRAPE 12PT	60	60							
0 LARGE ROUNDS 25LB	60	60							
0 ROMA 25LB	180	180							
0 SELECT 25LB UBU	10	10							
0 4X4	8	8							
0 4X5 CCF	40	40							
0 5x5 20LB LAYER	164	164							
0 6x6 25 LB	180	180							

187529 002 002 14061.22

COOL RYAN S/C FREIGHT ICE BLK CH

002 002 14061.22

Clauses of 41 CFR 60-1.4(a), 41 CFR 60-250.5(a), and 41 CFR 60-741.5 (e) as well as 29 CFR 1910.101-101.101 are incorporated by reference in all contracts and subcontracts, as applicable.

187529 002 002 14061.22

Distributor D Nashville TN

Far A

NASHVILLE, TN 37210 PHONE: 615-284-2888

P.O. #  
D.C. #  
CONFIRMED  
P.O. DATE  
PHONE #  
FAX #  
BROKER'S PHONE #  
BROKER'S FAX #  
P.O. Type

RECEIVING PURCHASE ORDER

TERMS: N/ LEAD: DAYS FRT:

CBO BROKER: BUYER: AN R.R. CARB: R.R. SEAL#:

SHIP / DELIVERY DATE: 4/25/2019

ITEM	QTY	UNIT	COOL	RYAN	S/C	FREIGHT	ICE	BLK	CH
0 CAPE CT UBU	170	170							
0 GRAPE 16LB	180	180							
0 GRAPE 12PT	60	60							
0 LARGE ROUNDS 25LB	60	60							
0 ROMA 25LB	180	180							
0 SELECT 25LB UBU	10	10							
0 4X4	8	8							
0 4X5 CCF	40	40							
0 5x5 20LB LAYER	164	164							
0 6x6 25 LB	180	180							

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COOL RYAN S/C FREIGHT ICE BLK CH

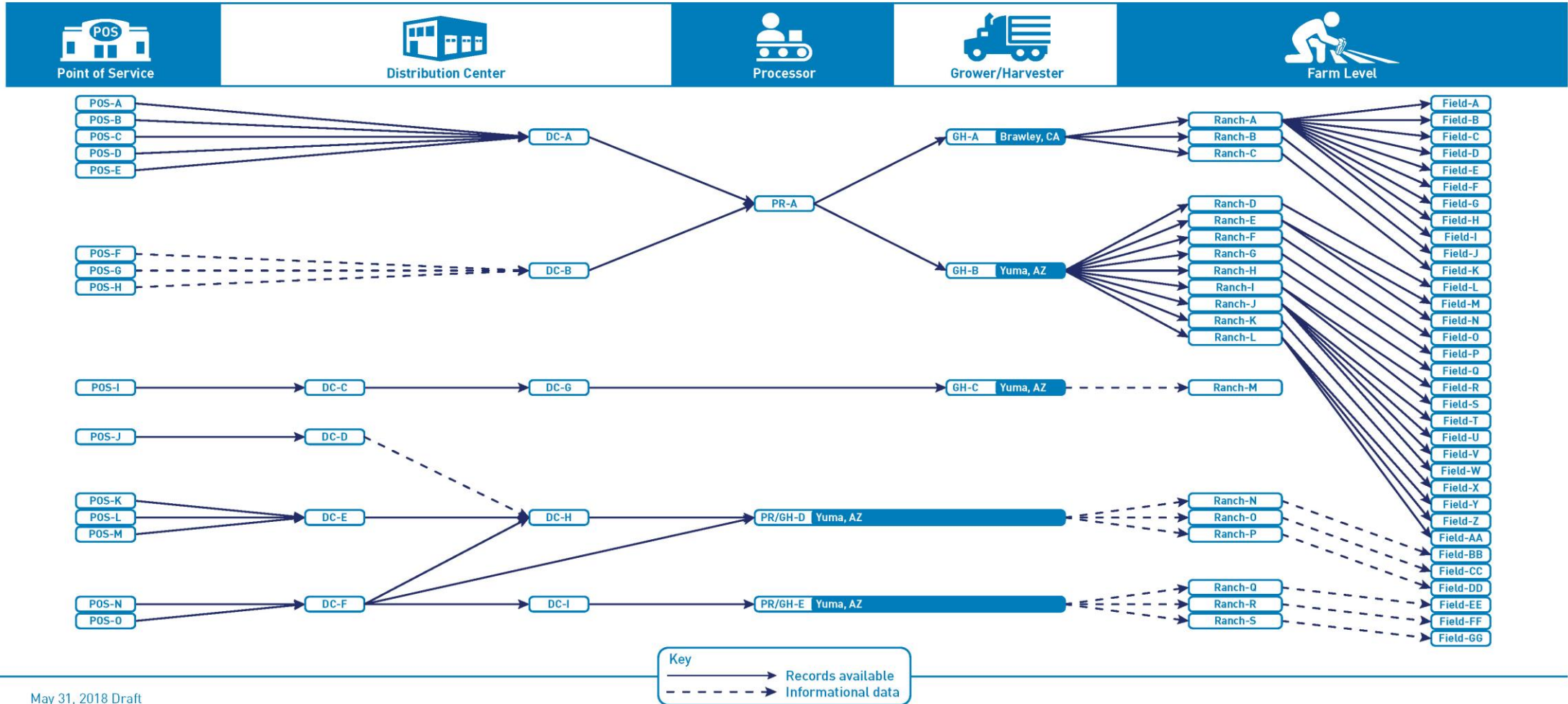
002 002 14061.22

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# Estado actual: Diagrama de Rastreo

E. coli O157:H7 – Romaine – Multi-state Outbreak  
Master Traceback Diagram

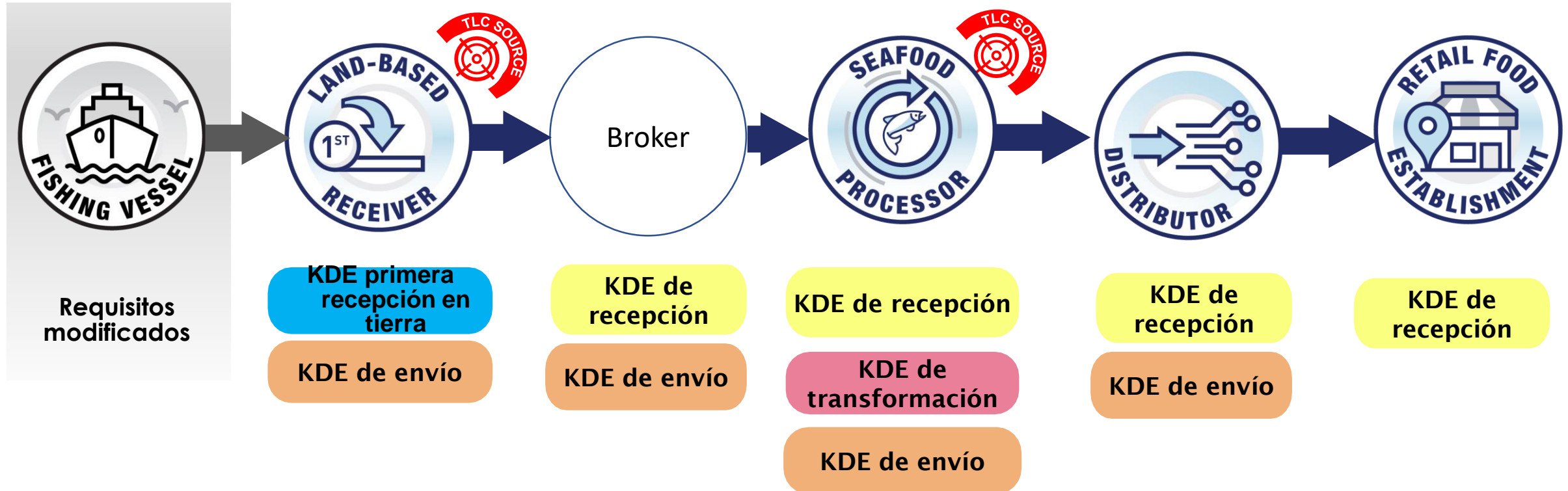


May 31, 2018 Draft

# Ejemplo: Cadena de Suministro de Lechuga Romana – Lechuga Entera Fresca



# Ejemplo: Cadena de suministro del Atún Salvaje, Ahumado



# Hojas de cálculo clasificables electrónicas



This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

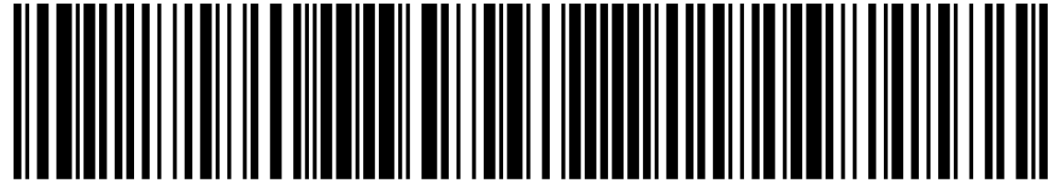
TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403.BIUB:12OCT2020	50 CASES	CHARLES CHEESE CO. BRAND FETA CHEESE 10 x 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	<a href="#">FFRN:456456</a>	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, <del>TLCville</del> , MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	<a href="https://id.gs1.org/01/11411411411402/10/FPP16-092420">https://id.gs1.org/01/11411411411402/10/FPP16-092420</a>	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	<a href="https://id.gs1.org/01/11411411411401/10/FPP16-092120">https://id.gs1.org/01/11411411411401/10/FPP16-092120</a>	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	<del>FreshFish</del> BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	<del>FreshFish</del> Importer Inc.	Distro Foodservice DC #45	9/22/2020	<a href="https://id.gs1.org/01/22322322322302/10/FFI2020-09-20">https://id.gs1.org/01/22322322322302/10/FFI2020-09-20</a>	BOL 22302

\*See Master Data Spreadsheet for full location descriptions

**Código de lote de trazabilidad:**

“(01)10223459999993(10)FPP16-091920”

Note: (01) = Número de Ítem Comercio Global (GTIN)  
(10) = Código de lote



(01)10223459999993 (10)FPP16-091920

**Garden / Salad Kit**  
**10x12oz, Bags**  
**USA**

Pack Date

**Nov 01**

14 **80**

**Marca Procesador Productos Frescos**  
Springfield, MA  
+1.800.999.9999

**Fuente de código de lote de trazabilidad (en página web):**

Co-Packer, Plant #16  
60 Elm Street  
Tomato City, FL 12345  
+1.818.818.8181

Gerente de inocuidad de los alimentos, fsm@fp.com

**Referencia de código de lote de trazabilidad (enlaces a página web, muestra la info de TLCS):**

<http://id.gs1.org/01/10223459999993/10/FPP16-091920>

*Calculado con hoja de cálculo a partir del TLC escaneado*

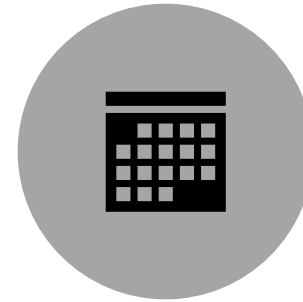
**Hoja de Cálculo clasificable electrónica (provista por Establecimiento Minorista de Alimentos al representante de la FDA si este**

Código de lote de trazabilidad	Descripción de la ubicación de la fuente previa inmediata	Descripción de la ubicación donde se recibieron los alimentos	Fecha de recepción, Reg Ref, Transportista	Cantidad y Unidad de medida (Info de producto)	Descripción de producto (Info de producto)	Referencia de Fuente de Código de Lote de Trazabilidad
(01) 10223459999993 (10)FPP16-091920	Food Distributors, DC #100 100 Main St., Anytown, GA 99999 +1.999.999.9999	Retailer Inc., Store #1052 222 Stone St., Anytown, SC 99999 +1.333.333.3333	11/08/2020 BOL 63264 Food retail Trucking	5 Cases	Garden Salad Kit, Fresh Processor Brand, 10 X 12 OZ Bags (Case GTIN: 10223459999993)	<a href="http://id.gs1.org/01/10223459999993/10/FPP16-091920">http://id.gs1.org/01/10223459999993/10/FPP16-091920</a> 15

## § 1.1455: Mantenimiento y disponibilidad de registros



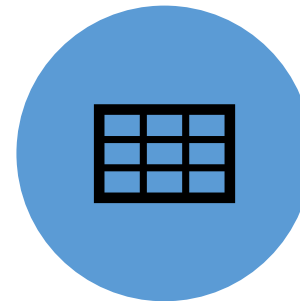
Copias **originales en papel o electrónicas**, o copias fieles. Almacenadas para prevenir su deterioro o pérdida. Puede **incluir enlaces electrónicos**.



Se deben mantener registros durante **2 años**.



Disponible dentro de las **24 horas (o un plazo razonable si lo acepta la FDA)**. Puede almacenarse **de manera externa o por otra entidad**.



Durante un brote – **hoja de cálculo clasificable** dentro de las 24 horas de la solicitud (incluida **una solicitud telefónica**).



# Página de inicio de la Norma de Trazabilidad de Alimentos



## FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

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Food Safety Modernization Act (FSMA)

Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

What's New in FSMA

FSMA Training

FSMA Technical Assistance Network (TAN)



Content current as of:  
11/17/2022

Regulated Product(s)  
Food & Beverages

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-](#)

# Herramienta de exenciones

## Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, ***unless*** an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms

Certain types of processing

Commingled raw agricultural commodities (RACs)

Personal consumption, holding food for specific consumers


Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants

# Herramienta KDE/CTE en el sitio web de la FDA

**Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)**




Harvesting
Cooling (before Initial Packing)
Initial Packing (RAC)
First Land-Based Receiver
Shipping
Receiving
Transformation
Traceability Plan

**Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)**

*KDEs must be linked to the traceability lot you assign for the food that you pack*

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the farm where the food was harvested
- For produce:
  - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
  - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
  - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
  - Other information identifying the harvest location at least as precisely as the container name
- Business name and phone number for the harvester of the food
- Date of harvesting
- Location description for where the food was cooled (if applicable)
- Date of cooling (if applicable)
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number

**Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)**




Harvesting
Cooling (before Initial Packing)
Initial Packing (RAC)
First Land-Based Receiver
Shipping
Receiving
Transformation
Traceability Plan

**Shipping KDEs (maintain and provide)**

*KDEs must be linked to the traceability lot for the food*

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

\*This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).



## Traceability

### Traceability Topics

- [The Food Traceability List \(FTL\)](#)
- [Risk-Ranking Model for Food Tracing \(RRM-FT\)](#)
- [Initial Packer](#)
- [First Land-Based Receiver](#)
- [Transformation](#)
- [Intracompany Shipments and Cross-Docking](#)
- [Farms](#)
- [Retail Food Establishments \(RFEs\)](#)
- [Comingled Raw Agricultural Commodities \(RACs\)](#)
- [Traceability Lot Code \(TLC\)](#)
- [Implementation](#)
- [Kill Step](#)
- [General](#)

### The Food Traceability List (FTL)

#### T.1 How did FDA determine which foods are included on the Food Traceability List (FTL)?

To determine which foods should be included on the FTL, the FDA developed a risk-ranking model for food tracing (“the Model”) based on factors that Congress identified in Section 204(d)(2) of the Food Safety Modernization Act (FSMA). The Model scores commodity-hazard pairs (e.g., Shiga toxin-producing *E.coli* O157 (STEC O157) in Leafy Greens) according to data and information relevant to seven criteria described in the report [Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204](#):

# Guía de Cumplimiento para Entidades Pequeñas

*Contains Nonbinding Recommendations*

**Requirements for Additional  
Traceability Records for Certain  
Foods:  
What You Need to Know About  
the FDA Regulation:  
Guidance for Industry**

**Small Entity Compliance Guide**

*Additional copies are available from:  
Office of Analytics and Outreach  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740*

<http://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry>

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-1336.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Analytics and Outreach**

May 2023



# Notificación en el Registro Federal

**70910** Federal Register / Vol. 87, No. 223 / Monday, November 21, 2022 / Rules and Regulations

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**

**21 CFR Part 1**  
**[Docket No. FDA-2014-N-0053]**  
**RIN 0910-A144**

**Requirements for Additional Traceability Records for Certain Foods**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).  
**DATES:** This rule is effective January 20, 2023. For the applicable compliance dates, see section VI “Effective and Compliance Dates” in the **SUPPLEMENTARY INFORMATION** section of this document.  
**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this final rule, into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.  
**FOR FURTHER INFORMATION CONTACT:**

Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).  
**SUPPLEMENTARY INFORMATION:**  
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**I. Executive Summary**  
 A. Purpose and Coverage of the Rule

accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.  
 We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)  
 B. Summary of the Major Provisions of the Final Rule  
 The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in

**§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?**  
 (a) Except as specified in paragraphs (b) and (c) of this section, for each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:  
 (1) The traceability lot code for the food;  
 (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);  
 (3) The product description for the food;  
 (4) The location description for the immediate previous source (other than a transporter) for the food;  
 (5) The location description for where the food was received;  
 (6) The date you received the food;  
 (7) The location description for the traceability lot code source, or the traceability lot code source reference; and  
 (8) The reference document type and reference document number.  
 (b) For each traceability lot of a food on the Food Traceability List you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:  
 (1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this paragraph does not apply if you are a retail food establishment or restaurant);  
 (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);  
 (3) The product description for the food;  
 (4) The location description for the immediate previous source (other than a transporter) for the food;  
 (5) The location description for where the food was received (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;  
 (6) The date you received the food; and  
 (7) The reference document type and reference document number.  
 (c) This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not

**§ 1.1350 What records must I keep when I transform a food on the Food Traceability List?**  
 (a) Except as specified in paragraphs (b) and (c) of this section, for each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:  
 (1) For the food on the Food Traceability List used in transformation (if applicable), the following information:  
 (i) The traceability lot code for the food;  
 (ii) The product description for the food to which the traceability lot code applies; and  
 (iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.  
 (2) For the food produced through transformation, the following information:  
 (i) The new traceability lot code for the food;  
 (ii) The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;  
 (iii) The date transformation was completed;  
 (iv) The product description for the food;  
 (v) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and  
 (vi) The reference document type and reference document number for the transformation event.  
 (b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b).  
 (c) Paragraphs (a) and (b) of this section do not apply to retail food establishments and restaurants with

**Procedures for Modified Requirements and Exemptions**  
**§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?**  
 (a) *General.* Except as specified in paragraph (b) of this section, FDA will modify the requirements of this subpart applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this subpart, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.  
 (b) *Registered facilities.* If a person to whom modified requirements or an exemption applies under paragraph (a) of this section (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under paragraph (a) of this section) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (and in accordance with the requirements of subpart H of this part) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.137 and 1.345. Such records must be maintained for 2 years.  
**§ 1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?**  
 FDA will consider modifying the requirements of this subpart applicable to a food or type of entity, or exempting a food or type of entity from the requirements of this subpart, on our own initiative or in response to a citizen petition submitted under § 10.30 of this chapter by any interested party.  
**§ 1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?**  
 In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting modified requirements or an exemption from the requirements of this subpart must:  
 (a) Specify the food or type of entity to which the modified requirements or exemption would apply;

# Red de Asistencia Técnica de FSMA

## FSMA Technical Assistance Network (TAN)



### Food Safety Modernization Act (FSMA)

Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

What's New in FSMA

FSMA Training

FSMA Technical Assistance Network (TAN)

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

### Frequently Asked Questions

The Technical Assistance Network staff has compiled answers to [frequently asked questions on FSMA](#). You may also use [FSMA Guidance Documents](#) to find answers to your questions.

### Submit Your Question Electronically

Didn't find your question above?

For assistance with **human food** topics, [submit your question to the TAN](#) .

For assistance with **animal food** topics, email the [CVM TAN Mailbox](#).

### Mail Your Question

If you prefer to mail in your question, please send it to the address below:

Food and Drug Administration  
5001 Campus Drive  
Wiley Building, HFS-009

Content current as of:  
09/09/2022

Regulated Product(s)  
Animal & Veterinary  
Food & Beverages

## Tech-enabled Traceability



## Smarter Tools and Approaches for Prevention and Outbreak Response



## New Business Models and Retail Modernization



## Food Safety Culture



# Ejemplo de Demo para Sistema de Rastreo de Productos



Food Traceability > 3APP Video Presentation > seafood example - clean

Name	Modified	Modified By	Comments	Add column
BITR - Acme Foodservice DC #45.xlsx	Tuesday at 9:46 AM	Broderick, Zachary		
ITE - Acme Foodservice DC #45.xlsx	Tuesday at 10:15 AM	Broderick, Zachary		
ITE - BigFish Bakers Inc.xlsx	Tuesday at 10:16 AM	Broderick, Zachary		
ITE - BigStore DC #21.xlsx	Tuesday at 10:20 AM	Broderick, Zachary		
ITE - BigStore Retail Store #1.xlsx	Tuesday at 10:22 AM	Broderick, Zachary		
ITE - Ca Mau Shrimp Farms.xlsx	Tuesday at 10:26 AM	Broderick, Zachary		
ITE - FreshFish Importer Inc.xlsx	Tuesday at 10:11 AM	Broderick, Zachary		
ITE - FrozenBreads Inc Plant #73.xlsx	Tuesday at 10:16 AM	Broderick, Zachary		
ITE - General Seafood Co Plant #88.xlsx	Tuesday at 10:21 AM	Broderick, Zachary		
ITE - Quoc Viet Shrimp Farms.xlsx	Tuesday at 10:23 AM	Broderick, Zachary		
ITE - Saffy Smokers.xlsx	Tuesday at 10:26 AM	Broderick, Zachary		
ITE - San Dupet Shrimp Farms.xlsx	Tuesday at 10:26 AM	Broderick, Zachary		
ITE - The Breakfast Bar Restaurant #32.xlsx	Tuesday at 10:26 AM	Broderick, Zachary		

# Desafío de trazabilidad asistida por tecnología

precisionFDA

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PREVIOUS PRECISIONFDA CHALLENGE

## The FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge

The Food and Drug Administration (FDA) calls on stakeholders, including technology providers, public health advocates, entrepreneurs, and innovators from all disciplines and from around the world, to develop traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end-user.

STARTS 06/01/2021 08:00:00 EDT ENDS 07/30/2021 17:00:00 EDT **Ended**

INTRODUCTION RESULTS

### News: Winner's Webinar!

On Tuesday, September 28, the top 12 performing teams shared their solutions and participated in a Q&A session. To watch the Webinar, please visit: <https://youtu.be/tnWMsF-qtIY>

### FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge Results

Introduction

Tapping into new technologies and integrating data streams will help to advance the widespread, consistent implementation of traceability systems across the food industry. However, the affordability of such technologies, particularly for smaller companies, can be a barrier to implementing tech-enabled traceability systems.

FDA's New Era of Smarter Food Safety initiative strives to work with stakeholders to explore low-cost or no-cost options so that our approaches are inclusive of and viable for human and animal food operations of all sizes. Democratizing the benefits of digitizing data will allow the entire food system to move more rapidly towards digital traceability systems.

Challenge Ended

News: Winner's Webinar

On Tuesday, September 28, the top 12 performing teams shared their solutions and participated in a Q&A session. To watch the Webinar, please visit: <https://youtu.be/tnWMsF-qtIY>

FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge Results

Introduction

Overview of Results

Evaluation

Results

Honorable Mentions

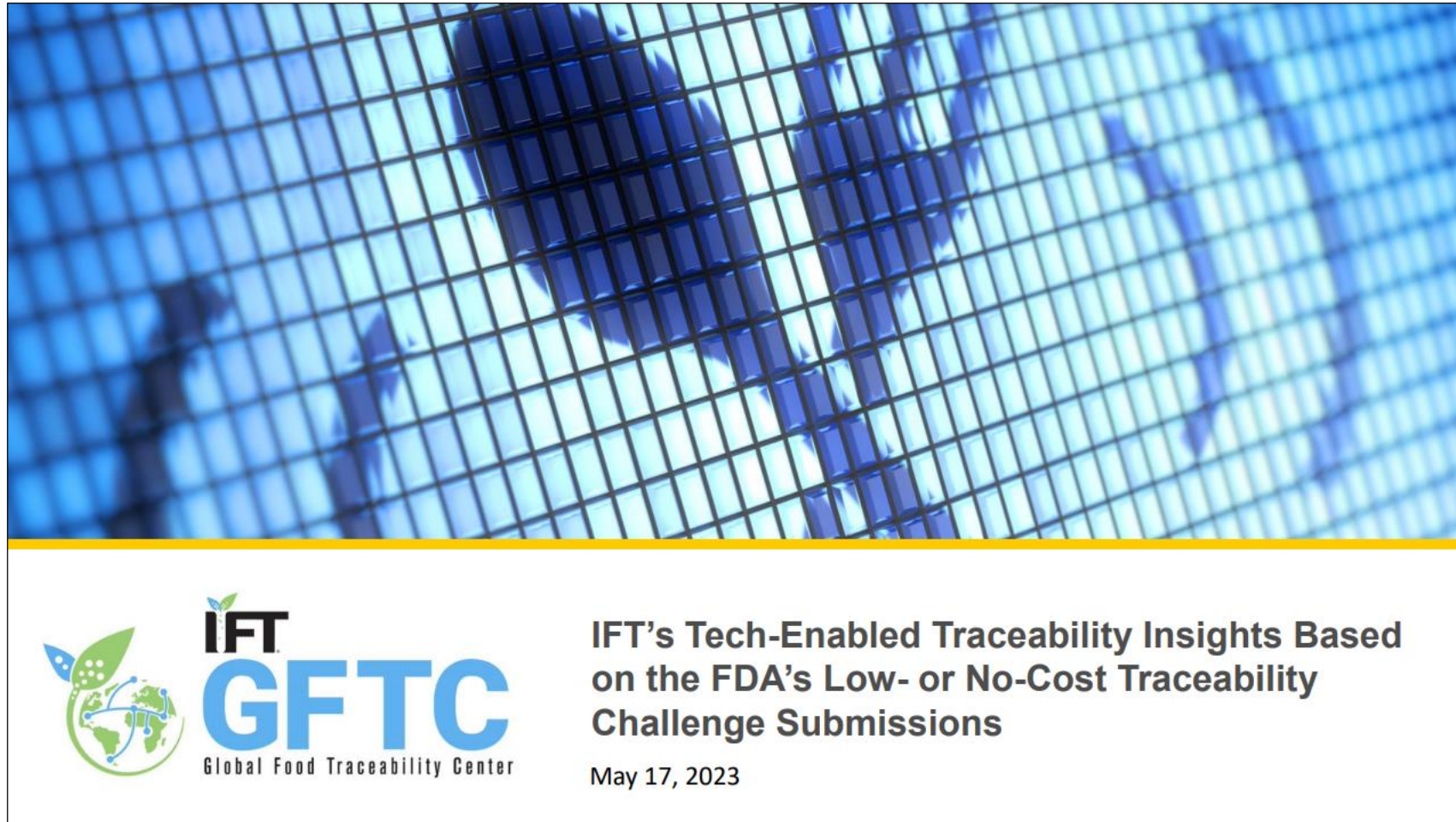
## Overview of Results

The challenge went live on June 1, 2021 and ran until July 30, 2021. There were a total of 90 submissions received from 90 unique teams. Teams hailed from Australia, Canada, China, England, France, Germany, India, Ireland, New Zealand, Singapore, Spain, Switzerland, Taiwan, and the United States (Figure 1). The majority of submissions (~72%) came from the United States.



Figure 1. Heat map showing locations of challenge participants

# Informe de trazabilidad asistida por tecnología del IFT



# Charla técnica sobre Trazabilidad de la FDA

## TechTalk Podcast Episode 1: Tech-enabled Traceability in the New Era of Smarter Food Safety

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From left to right: Angela Fernandez (GS1 US); Alison Grantham, Ph.D. (IFT); Hilary Thesmar, Ph.D., RD, CFS (FMI)

Content current as of:  
04/29/2021

Regulated Product(s)  
Food & Beverages

# Proyectos piloto sobre trazabilidad de vegetales de hoja verde 2020

## Leafy Greens Action Plan Tech Enabled Traceability

2020 Leafy Green Pilot **FINAL REPORT**

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Point of Sale	Distribution Center	Processor	Farm Level
---------------	---------------------	-----------	------------

Within 24 hours of being contacted by the Pilot Team 1, the retailer was able to provide details of the purchase and shopper card information. The paperwork containing the information requested by Team 1 was provided within roughly 31 hours, but the retailer needed an additional 2 days to enter the necessary information into the template. In the interim, Team 1 remained in communication with the retailer, and provided additional education and explanation regarding the template. Each of the pilot participants provided comments on the template, and a key learning from the first pilot was that the template was not intuitive and required explanation. This is further discussed below.

There was an 8-day delay in the progression of Pilot 1 while waiting for the fresh-cut processor to sign the NDA. Clearly, companies responding to FDA requests will not need to sign an NDA, so this time is not counted against the total time to conduct the pilot. The fresh-cut processor was able to provide complete information, including details of the grower, ranch, field, subplot, harvest date, and in most cases harvest crews. The fresh-cut processor received a request for data related to the shipments received by the retailer on a Friday and returned the completed template the following Monday.

# Documento Guía sobre Trazabilidad GS1 US



# Podcast “Food Safety Matters” (La inocuidad alimentaria importa)



## Friedlander and Lasprogata: FDA and Industry Perspectives on FSMA 204

January 31, 2023

Part of *Food Safety Magazine's* series with the U.S. Food and Drug Administration (FDA), titled, “Evolution of a New Era: Advancing Strategies for Smarter Food Safety,” this episode of *Food Safety Matters* discusses improving traceability and transparency in the food supply chain through the implementation of the Final Food Traceability Rule, as mandated by Congress under the Food Safety Modernization Act (FSMA) Section 204. We are joined by Adam Friedlander, Policy Analyst in FDA’s Coordinated Outbreak Response and Evaluation (CORE) Network, and Joseph Lasprogata, Vice President of New Product Development at Samuels Seafood.

# Recursos AFDO SHOP



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## Leveraging Food Purchase History to Solve Foodborne Outbreaks

CATEGORY: [FOODBORNE OUTBREAK](#) , [SHOPPER CARD - PURCHASE HISTORY](#)



The Shopper History Outbreak Partnership (SHOP) is a group of public health and food safety officials dedicated to working closely with industry partners to use consumer food purchase data as a tool to solve foodborne outbreaks, remove contaminated food from the marketplace, and prevent additional illnesses.





**Juntos, podemos bajar la curva de las enfermedades transmitidas por alimentos**

**¡Gracias!**

